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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,422	10/30/2003	Karl Cazzini	2527US	7224

26356 7590 10/04/2005

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EXAMINER
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SHAY, DAVID M

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 10/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	Application No. 10/697,422	Applicant(s) CAZZINI ET AL.	
	Examiner david shay	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on February 3, 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-84 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-84 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on October 30, 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>February 3, 2004</u> .  | 6) <input type="checkbox"/> Other: _____                                    |

The drawings are objected to because The drawings are objected to because the quality of Figures 1 and 4 are extremely poor, it is virtually impossible to determine what is intended to be shown; Figure 2 is improperly oriented, as the indicia would not be right side up if the figure were rotated to the right by 90 degrees; in all Figures, the indicia are blurry and not evenly dark. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "plurality of microbubbles displaced within the polymer matrix"; the "circular or semi-ellipsoidal incident surfaces"; "the optical cable comprises a plurality of optical fibers"; "the optical cable gauges is equal to the gauge of the optical fiber"; "the optical fiber is operatively connected to the handpiece to enable

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linear displacement of the optical fiber and the small gauge optical element within the cannula”; “the handpiece comprises a means for adjusting the linear displacement”; “the adjusting means comprises a push/pull mechanism”; “adjusting the linear displacement adjusts the small-gauge optical element position relative to the open aperture”; “the amount of linear displacement of the small-gauge optical element determines an angle of illumination and an amount of illumination”; “the angle of illumination can be varied between about 20 degrees to greater than about 180 degrees”; “one or more optical filters”; “the light source is a xenon or a halogen light”; “the plurality of microbubbles is randomly distributed”; “the plurality of microbubbles each have a diameter of about 1 to 50 microns”; and “the plurality of microbubbles is distributed with a distribution density operable to scatter and transmit the light beam in an isotropic manner” must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will

be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Applicant is required to cancel the new matter in the reply to this Office Action.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 22, 23, 49, 50, 77, and 78 rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The tissue of the surgical environment is a part of the body.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-84 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The originally filed disclosure does not enablingly describe how “plurality of microbubbles displaced within the polymer matrix”; the “circular or semi-ellipsoidal incident surfaces”; “the optical cable comprises a plurality of optical fibers”; “the optical cable gauges is equal to the gauge of the optical fiber”; “the optical fiber is operatively connected to the handpiece to enable linear displacement of the optical fiber and the small gauge optical element within the cannula”; “the handpiece comprises a means for adjusting the linear displacement”;

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“the adjusting means comprises a push/pull mechanism”; “adjusting the linear displacement adjusts the small-gauge optical element position relative to the open aperture”; “the amount of linear displacement of the small-gauge optical element determines an angle of illumination and an amount of illumination”; “the angle of illumination can be varied between about 20 degrees to greater than about 180 degrees”; “one or more optical filters”; “the light source is a xenon or a halogen light”; “the plurality of microbubbles is randomly distributed”; “the plurality of microbubbles each have a diameter of about 1 to 50 microns”; and “the plurality of microbubbles is distributed with a distribution density operable to scatter and transmit the light beam in an isotropic manner” are achieved.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-23, 49, 50, 77, and 78 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-29 are indefinite because the preamble of the claim is of a different scope than the body thereof, in that the preamble merely recites an optical element and the body of the claim recites for example such elements as an optical fiber; optical cable; cannula; and light source, which are not properly parts of the optical element. Claims 22, 23, 49, 50, 77, and 78 are indefinite as they fail to further limit the claim from which they depend, as they recite the surgical environment, which is not properly part of the device and therefore what further limitation is intended to be implied is unclear. Claims 30-56 and 57-84 are indefinite because what the differences is between these claim sets is unclear.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Hemphill.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11, 22-38, 49-66, and 77-84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turner in combination with Bahmanyar et al and Knowles et al. Turner teaches a device as claimed except for the use of microlenses per se; a circular or semi-ellipsoidal surface; the optical cable comprising two SMA connectors; the microlenses being 1 to 50 microns in diameter; and the optical element being 2 millimeters long. Bahmanyar et al teach the equivalence of microlenses and holographic elements, the use of connecting cables with multiple fibers and two SMA connectors. Knowles et al teach that microbubbles function as microlenses. It would have been obvious to the artisan or ordinary skill to employ microlenses in the place of the holographic element of Turner, since these are equivalents, as taught by Bahmanyar et al; to form the microlenses as microbubbles, since microbubbles are known in the art of optics to behave in this manner, as taught by Knowles et al, and to form the optical element to have a circular or semi-ellipsoidal surface, to be 2 millimeters long, so as to not unduly

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enlarge the device, and to have microbubbles between 1 micron and 50 microns in diameter, so as to render the microbubbles small enough to enable the light beam to interact with a large number of them, and since all these features are well known in the art; are well within the scope of one having ordinary skill in the art, and provide no unexpected result, thus producing a device and method such as claimed.

Claims 12-18, 39-45, and 67-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turner in combination with Bahmanyar et al and Knowles et al as applied to claims 1-11, 22-38, 49-66, and 77-84 above, and further in combination with Pankratov et al. Pankratov et al teach a device with a fiber that is longitudinally translatable to change the size of the illuminated area. It would have been obvious to the artisan of ordinary skill to provide the linear displacement means of Pankratov et al in the device of Turner, since this would allow the illuminated area to be changed much more rapidly than by the optical element switching technique of Turner, which would require the device to be withdrawn from the eye, thus providing a shorter operation, which is desirable as it reduces the amount of stress on the physician and patient, official notice of which is hereby taken, and to situate the distal end of the optical element so as to be coincident with the distal end of the cannula, as this is well within the scope of one having ordinary skill in the art, maximizes the light output, and provides no unexpected result and to allow the angle of illumination to be varied between about 20 degrees to greater than about 180 degrees, as this is well within the scope of one having ordinary skill in the art, would allow a wide variety of surgical fields to be illuminated, and provides no unexpected result, thus producing a device such as claimed.

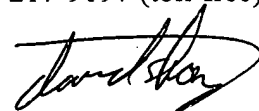


Claims 19-21, 46-48, and 74-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turner in combination with Bahmanyar et al and Knowles et al as applied to claims 1-11, 22-38, 49-66, and 77-84 above, and further in combination with Fritch et al. Fritch et al teach the use of filters and a broad band light source to provide illumination for ocular surgery. It would have been obvious to the artisan of ordinary skill to employ the broad band illuminating source and filters of Fritch et al in the device of Turner, since Turner discloses no particular source, and to employ a xenon or halogen lamp, since these are well known for use in ophthalmic devices, as they provide bright light, official notice of which is hereby taken, thus producing a device such as claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Tuesday through Thursday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader, can be reached on Monday, Tuesday, Wednesday, and Friday. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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